NO. 73020-2

SUPREME COURT OF THE STATE OF WASHINGTON

WASHINGTON EMPLOYERS CONCERNED ABOUT REGULATING ERGONOMICS, et al.,

Appellants,

v.

WASHINGTON DEPARTMENT OF LABOR AND INDUSTRIES,

Respondent,

AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS AND WASHINGTON STATE LABOR COUNCIL, AFL-CIO

Intervenors.

BRIEF OF INTERVENORS AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS AND WASHINGTON STATE LABOR COUNCIL, AFL-CIO

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BRIEF OF INTERVENORS AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS AND WASHINGTON STATE LABOR COUNCIL, AFL-CIO

I. INTRODUCTION

This case concerns the Washington Department of Labor and Industries' (the Department's) effort to address the most common cause of workplace injuries and illnesses to working men and women in Washington -- workplace hazards that cause back injuries, carpal tunnel syndrome, rotator cuff syndrome, tendonitis, and other related musculoskeletal disorders (MSDs).[1] More than 50,000 working men and women in Washington suffer work-related MSDs -- "WMSDs" -- each year, resulting in widespread pain, disability, expense, and personal hardship. The direct and indirect cost of these injuries is $1.1 billion each year. Washington Department of Labor

[1] The ergonomics rule defines WMSDs as "[w]ork-related disorders that involve soft tissues such as muscles, tendons, ligaments, joints, blood vessels and nerves. Examples include: muscle strains and tears, ligament sprains, joint and tendon inflammation, pinched nerves, degeneration of spinal discs, carpal tunnel syndrome, tendonitis, rotator cuff syndrome. For purposes of this rule WMSDs do not include injuries from slips, trips, falls, motor vehicle accidents or being struck by or caught in objects." WAC 296-62-05150. A copy of the ergonomics rule is attached to the Department's brief as Appendix 1.

and Industries, Concise Explanatory Statement for WAC 296-62-051, Ergonomics (May 25, 2000) (CES) at 2, Administrative Record (AR) at 117632.[2]

To address this pervasive problem, the Department adopted an ergonomics rule designed to reduce or eliminate the workplace hazards that lead to WMSDs.[3] Drawing on comprehensive reports by expert bodies such as the National Academy of Sciences and the National Institute for Occupational Safety and Health, hundreds of published scientific studies, survey research of Washington State employer practices, data from the state workers' compensation system, and other sources, the Department crafted an ergonomics rule that mirrors the approach to addressing workplace hazards in many other WISHA rules. The Department reviewed the record evidence and concluded that the ergonomics rule will prevent tens of thousands of WMSDs each year. The Department determined that the rule's benefits will exceed its costs by more than a 4 to 1 margin

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[2] A copy of the CES is attached to the Department's brief as Appendix 2.

[3] Throughout this brief, we refer to workplace hazards that can cause or aggravate musculoskeletal injuries as "WMSD hazards."

through reduced workers' compensation payments, productivity improvements, and other savings. CES at 4.

Appellants WECARE, et al., (WECARE or the Companies), a coalition of state and national business interests, challenge the ergonomics rule, contending that it fails to meet the requirements of the Administrative Procedure Act (APA) and the Washington Industrial Safety and Health Act (WISHA). The Companies seek a radical departure from the standard of review traditionally used by this court in evaluating agency rules, and they ask this court to impose an unprecedented evidentiary burden on agencies such as the Department when they adopt preventive safety and health regulations like the ergonomics rule at issue in this case.

WECARE's arguments are utterly contrary to the language, purpose and history of the APA and WISHA, and contrary to this court's precedent. Their challenge should be rejected, and the ergonomics rule should be upheld.

II. COUNTER-STATEMENT OF THE ISSUES

Intervenors adopt the Department's counter-statement of the issues. Department's Brief at 3.

III. SUMMARY OF ARGUMENT

WISHA was adopted "to assure, insofar as may reasonably be possible, safe and healthful working conditions for every man and woman working in the state of Washington." RCW 49.17.010. In furtherance of that purpose, WISHA directs the Department to adopt safety and health standards to protect workers from workplace hazards. RCW 49.17.040, .050. Standards adopted by the Director must be reasonably necessary and appropriate to protect workers, RCW 49.17.020(7), they must be feasible, RCW 49.17.050, and they must be based on the "best available evidence." *Id.* Rules must provide the maximum level of protection to workers over their working lives, within the bounds of economic and technological feasibility. *Id.*

The standard for judicial review of agency rules is set forth in the Administrative Procedure Act:

> In a proceeding involving review of a rule, the court shall declare the rule invalid only if it finds that: The rule violates constitutional provisions; the rule exceeds the statutory authority of the agency; the rule was adopted without compliance with statutory rule-making procedures; or the rule is arbitrary and capricious.

RCW 34.05.570(2)(c).[4] The burden of demonstrating the rule's invalidity is on the party challenging the rule. RCW 34.05.570(1)(a).

Amendments to the APA adopted by the Legislature in 1995 added a number of requirements on agencies before they adopt "significant legislative rules." RCW 34.05.328. For example, agencies now must make a determination that a significant legislative rule is needed and that the rule's benefits will exceed its costs. *Id.*

The ergonomics rule satisfies each of these statutory tests. The rule was adopted in full conformance with WISHA and the APA. WECARE's challenge should be rejected.

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[4] Intervenors fully concur with the Department that the "arbitrary and capricious" standard of review set forth in RCW 34.05.570(2)(c) applies to this proceeding, and not the "reasonable person" test urged by the Companies. The "reasonable person" language relied on by WECARE appears in an entirely different section of the APA – a section which describes additional burdens on *agencies* in adopting significant legislative rules, not the standard of review to be used by reviewing courts. *Compare* RCW 34.05.570(2)(c) (Judicial Review) *with* RCW 34.05.328 (Significant Legislative Rules). Moreover, shifting the burden of proof to the agency, as WECARE's interpretation would do, conflicts with the clear language of the APA, which places the burden of proving a rule's invalidity squarely on the person challenging the rule. RCW 34.05.570(1)(a).

This brief will not address each of WECARE's myriad claims, which have been thoroughly rebutted by the Department in its brief, but rather will focus on key flaws in several of WECARE's principal arguments.

IV. ARGUMENT

The Washington Industrial Safety and Health Act (WISHA) was enacted to "assure, insofar as may reasonably be possible, safe and healthful working conditions for every man and woman working in the state of Washington." RCW 49.17.010.

WISHA directs the Department to adopt safety and health standards to protect workers from workplace hazards, RCW 49.17.040, RCW 49.17.050, and to issue citations, including financial penalties, for violations of these rules. RCW 49.17.060. WISHA is a preventive statute aimed at addressing workplace hazards and reducing the toll of workplace injuries and illnesses. WISHA, like its federal counterpart, "does not wait for an employee . . . [to] become injured [before addressing workplace hazards]. It authorizes the promulgation of health and safety standards . . . in the hope that these will act to prevent . . . injuries from ever occurring."

Forging Industry Ass'n v. Secretary of Labor, 773 F.3d 1436, 1443 (4th Cir. 1985) (*quoting Whirlpool Corp. v. Marshall*, 445 U.S. 1, 12 (1980)).

A. Adoption of an Ergonomics Rule to Prevent Work-Related MSDs was Well Within the Department's Statutory Authority

WISHA directs the Department to adopt "health and safety standards" to protect workers from harm. RCW 49.17.020, .040, .050. It was plainly within the Department's statutory authority to adopt a rule to address the leading cause of workplace injuries in the state. The Companies' contrary interpretation of RCW 49.17.050 flies in the face of the plain language and obvious purpose of the statute.[5]

The need for an ergonomics rule is compelling. Every year, more than 50,000 men and women in the State of Washington are injured at their workplaces because their jobs entail heavy lifting, highly repetitive work, awkward movements, and other WMSD

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[5] Intervenors join with the Department's other arguments on this point. Department's Brief at 17-20.

hazards.[6] CES at 2, AR at 117632. Nurses' aides in nursing homes and nurses in hospitals injure their backs when they are lifting and otherwise assisting patients. CES at 84, AR at 117714. Assembly line workers whose jobs involve frequent, awkward movements experience rotator cuff injuries, carpal tunnel syndrome, tendonitis, and other injuries. CES at 79, 88, AR 117709, 117718. Workers whose jobs involve extensive computer use contract carpal tunnel syndrome and other hand and wrist disorders from hazards involved in extensive keyboard work. CES at 82, AR 117712. Workers in nearly every industry and occupation suffer crippling back injuries, carpal tunnel syndrome, and other musculoskeletal disorders at alarming rates. CES at 94-105, AR 117724-117735. Working women are disproportionately affected by certain types of MSDs, particularly those affecting the hands and wrists, such as carpal

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[6] These numbers are based on accepted workers' compensation claims. CES at 31. The Department observed in the CES that workers' compensation data tends to underestimate the extent of the MSD problem. CES at 35.

tunnel syndrome.[7]

Washington workers face a much greater risk of being injured from WMSD hazards than from other common hazards on the job. Each year, 1.34% of the workforce suffers work-related MSDs. CES at 33, AR 117663. This is more than six times the rate for job-related bone fractures. *Id.* And, it is more than 40 times the rate for work-related burns.[8] *Id.* The risk of being injured in a job-related motor vehicle accident, although a serious concern, is a mere fraction of the risk of suffering a work-related MSD. *Id.*

Indeed, work-related MSDs are the largest category of workplace injuries and illnesses affecting Washington workers, and, prior to the adoption of the ergonomics rule, the most significant unregulated workplace safety and health risk. CES at 2, AR 117632.

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[7] Sixty-one percent of workers' compensation claims for carpal tunnel syndrome are filed by women. AR 114235. These claims have an average direct cost of $12,627, and involve an average of 209 days lost from work per compensable claim. *Id.* Similarly, approximately 60 percent of the claims filed for hand/wrist MSDs between 1990-1998 were filed by women. AR 114236. The percentage of workers' compensation claims for MSDs filed by women workers increased between 1990 and 1998. AR 114254.

[8] A description and chart showing the comparative risk of MSDs and other common workplace injuries can be found at pages 33 and 34 of the CES, AR 117663-64.

The financial and human toll these injuries impose on workers, employers, and the state is staggering. Work-related MSDs cost Washington employers an estimated $410 million each year in direct costs such as medical costs and partial wage replacement. CES at 36, AR 117666. When indirect costs, such as lost productivity and lost work time are included, the annual cost to employers rises to $1.1 billion each year. *Id.* These numbers do not include the substantial costs borne by workers, in the form of lost wages, out-of-pocket medical expenses, and other costs. *Id.*

MSDs are serious injuries. The average cost of an upper extremity MSD workers' compensation claim is $5,837. AR 114234. Other MSDs -- including rotator cuff injuries (average cost per claim of $15,226), carpal tunnel syndrome (average cost per claim of $12,627) and sciatica of the back (average cost per claim of $39,371) – are considerably more costly. AR 114264. Of course, the bare amount of a workers' compensation award cannot begin to

reflect the incalculable but significant human suffering such an injury imposes on the worker and his or her family.[9] AR 200829-32.

In short, the rulemaking record all but compels the conclusion reached by the Department that an ergonomics rule is "reasonably necessary or appropriate to provide safe or healthful employment and places of employment" for working men and women in the state. RCW 49.17.020(7). If anything, the ergonomics rule is under protective in several key respects. The rule fails to address certain WMSD risk factors, such as whole body vibration, or pushing, pulling, and carrying heavy or awkward objects. CES at 24-25, AR

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[9] Dozens of workers testified during the ergonomics rulemaking and vividly described the impact that work-related MSDs have had on their lives and on their families. See, e.g., AR 200858-59 (testimony of Joanne Keenan); AR 200829-32 (testimony of Lila Smith); AR 200805-08 (testimony of Ingrid Rasmussen). Lila Smith described the impact of shoulder and elbow injuries she incurred while working as a ticket seller for Washington State Ferries:

> I couldn't push a vacuum cleaner; I couldn't pull weeds in the garden; I couldn't brush my teeth with a regular toothbrush; I had to buy an electric toothbrush and hold it with two arms. . . . I couldn't hold a knife . . . long enough, hard enough to chop an onion; and it hurt to put a sweater on over my head. . . . My kids had a hard time, too. I looked normal, so they didn't understand why I couldn't go to the grocery store alone. I couldn't push the grocery cart. This is not a trivial problem.

117654-55. It allows employers an extremely – Intervenors would say excessively – generous phase-in period, giving many employers up to *six years* before they are required to eliminate or reduce hazards to the extent feasible. WAC 296-62-05160. The Department would have been justified in requiring more comprehensive, and quicker, protection from this pervasive hazard. Still, notwithstanding its excessively generous phase-in schedule and its failure to address certain WMSD risk factors, the ergonomics rule will prevent thousands of crippling MSDs, sparing workers, their families, and employers in this state significant hardship and cost.

B. The Ergonomics Rule Follows the Traditional Approach to Workplace Safety and Health Regulation

The basic requirements of the ergonomics rule are as follows. The rule requires employers to determine whether employees work in "caution zone jobs," defined by the rule as jobs that involve exposure to specified WMSD "risk factors" such as highly repetitive work or awkward lifting, at specified levels, for a specified amount

of time. WAC 296-62-05105.[10]

If an employer has employees in "caution zone" jobs, the employer must determine whether the jobs pose WMSD hazards, as defined by the rule. WAC 296-62-05130.[11] If WMSD hazards exist, employers must reduce or eliminate the hazards, to the extent technologically and economically feasible. WAC 296-62-05130. The rule does not dictate the sort of equipment or job modifications employers are to use in reducing or eliminating WMSD hazards, but allows employers flexibility in designing interventions for their particular workplace. Employers must provide basic training to employees working in or supervising "caution zone" jobs. WAC 296-62-05120, 05122.

This approach -- requiring employers to survey their workplace for hazards, to institute controls when workers are exposed to a hazard, and to train affected workers – is the same

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[10] The Department estimates that 78 percent of jobs fall outside the "caution zone." Washington Department of Labor and Industries, Cost-Benefit Analysis of the Ergonomics Standard (May 2000) (hereafter CBA), Appendix D, AR 118122. A copy of the CBA is attached to the Department's brief as Appendix 3.

[11] The Department estimates that 12 percent of employees work in jobs with MSD hazards as defined by the ergonomics rule. CBA, Appendix D, AR 118122.

approach taken in myriad health and safety rules. Requiring employers to identify whether they have any "caution zone jobs" is analogous to requiring employers to survey their workplace to determine whether workers are exposed to a toxic substance at an "action level," or whether equipment posing safety hazards is present, as is required by many other standards. *See, e.g.*, WAC 296-62-077 (asbestos), WAC 296-62-7523 (benzene), WAC 296-62-07361 (ethylene oxide), WAC 296-62-07540 (formaldehyde), WAC 296-24-11001 (lockout of hazardous machinery), WAC 296-67-001 (process safety management). And, requiring employers to reduce or eliminate a workplace hazard, whether defined in numerical terms such as a permissible exposure limit or in more descriptive terms, is the settled approach to regulating a workplace hazard. *Id.*

What is more, the approach adopted by the Department reflects the approach recommended by the National Institute for Occupational Safety and Health for addressing the specific problem

of WMSD hazards.[12] *See also* U.S. General Accounting Office, "Worker Protection: Private Sector Ergonomics Programs Yield Positive Results," GAO/HEHS-97-163 (Aug. 1997), AR 113892 (experts agree that effective ergonomics programs contain core elements, including identification of problem jobs, development of solutions, training and education, and employee involvement). The Department was well within its statutory authority in following this approach with the ergonomics rule.

C. The Department's Determination that an Ergonomics Rule was Needed to Protect Workers was Based on the Best Available Evidence

The rulemaking file provides overwhelming support for the Department's determination that the ergonomics rule is needed to protect workers from a serious workplace hazard. That record – including reports by prestigious scientific bodies such as the National Academy of Sciences (NAS) and the National Institute for

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[12] In 1997, NIOSH issued a comprehensive guide to ergonomics based on NIOSH's "extensive practical experience" in investigating WMSD hazards and recommending solutions. NIOSH, "Elements of Ergonomics Programs: A Primer Based on Workplace Evaluations of Musculoskeletal Disorders," (March 1997), AR 115361-115501. According to NIOSH, the "key elements of an effective [ergonomics] program" include management commitment, worker participation, training, and the identification, evaluation, and control of ergonomic risk factors. AR 115365-366.

Occupational Safety and Health (NIOSH), data on the nature and extent of WMSDs in Washington state, and hundreds of scientific studies – provides ample justification for the Department's conclusion that workplace exposure to WMSD hazards leads to serious injuries that can be significantly reduced through the sort of ergonomics interventions required by the rule.[13]

In adopting the ergonomics rule, the Department was required to make a determination that the rule was "reasonably necessary or appropriate to provide safe or healthful employment." RCW 49.17.020(7). "Whether regulations are reasonable or appropriate is a question for the fact finder to determine on a case-by-case basis, subject to only limited review by this court." *Aviation West Corp. v. Dept. of Labor and Industries*, 138 Wn.2d 413, 432, 980 P.2d 701 (1999); *see also Rios v. Dept. of Labor and Industries*, 145 Wn.2d

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[13] This court has specifically approved reliance on expert agency reports in assessing the need for protective regulations. *Aviation West Corp. v. Dept. of Labor and Industries*, 138 Wn.2d 413, 426, 980 P. 2d 701 (1999) ("[c]hoosing to not 'reinvent the wheel' and instead relying upon existing . . . studies that are directly on point appears to us to be a reasonable decision"). Even if "none of the reports . . . advocated the type of [] regulation" ultimately adopted, the Department is permitted to rely on them as the best available evidence if "they clearly provided evidence from which a reasonable conclusion could be drawn that such a regulation is necessary to protect worker health." *Id.*, at 429.

483, 501, 39 P.3d 961 (2002). The Department was required to use the "best available evidence" in making this determination. RCW 49.17.050(4).

The Companies assert that the Department violated the "best available evidence" requirement by "rel[ying] almost exclusively" on epidemiological studies in determining the need for the ergonomics rule. Companies' Brief at 43.[14] The Companies contend that this epidemiological evidence is "fundamental[ly] unreliab[le]", and that "superior evidence" identified by the

[14] "Epidemiology is the science that studies the incidence and distribution of diseases or injuries in populations rather than individuals. Its conclusions depend on statistical associations between exposure and outcome." CES at 7. As such, epidemiological evidence cannot establish causation of a particular injury. Nevertheless, "[e]pidemiology provides a preferred body of scientific information for occupational safety and health decision making because the data derives from real workplace circumstances and does not require extrapolation from laboratory to workplace or from animals to humans." *Id.* at 8. *See also UAW v. Pendergrass*, 878 F.2d 389, 394 (D.C. Cir. 1989) (noting OSHA's "general preference for epidemiological data" over animal studies).

Companies "undermines the Rule." *Id.*[15] In particular, WECARE criticizes the Department for not basing its conclusions on a particular type of evidence -- namely, randomized controlled trials (RCTs) – that WECARE contends undermine the premises of the ergonomics rule.[16]

In its brief, the Department responds extensively to the Companies' claims, explaining that it could not rely on hypothetical evidence and that the three RCT studies cited by WECARE were

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[15] WECARE's attempt to dismiss the epidemiological evidence on ergonomics as "junk science" is off base. Companies' Brief at 40. The admissibility of epidemiological evidence under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed. 2d 469 (1993) in any particular tort case has nothing to do with the "best available evidence" supporting a protective regulation to prevent workplace injuries.

Similarly, WECARE's attempt to undermine the Department's reliance on epidemiology in this rulemaking by pointing out that the Department has argued against the use of population-based research in making individual workers' compensation determinations, *see* Companies' Brief at 46, shows nothing more than that the Department – unlike the Companies – understands epidemiology's proper place.

[16] As the Department points out in its brief, RCTs are a type of epidemiology and "compare the incidence of disease among a group of people exposed to a potential hazard with a randomly selected unexposed control group." Department's Brief at 32, n.22.

irrelevant or flawed. Department's Brief at 29-34.[17] Contrary to the Companies' claims, RCTs are not the "best available evidence" (or, as WECARE would say, the "gold standard") for the adoption of an ergonomics rule, either in theory or on this record.[18]

The evidence in the rulemaking record – evidence of a depth, variety, and richness rarely available in WISHA rulemaking -- provides overwhelming support for the ergonomics rule. The notion that the Department should be precluded from taking action to protect workers based on this record, and instead should be required to await the results of hypothetical future RCTs, has no place under WISHA. WECARE can point to no case where a workplace safety and health standard was invalidated for lack of RCT evidence. Rather, this court, and federal courts, have routinely upheld WISHA and OSHA rules whose findings of risk to workers were based on

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[17] The Department also explained that the epidemiological studies were but one body of information it relied on in determining that the ergonomics rule was needed to protect workers. In addition to drawing on expert reports by NIOSH and the NAS, the Department had available to it, and utilized, a rich pool of workers' compensation data showing the extent of MSD injuries among workers in Washington State. Department's Brief at 23-28.

[18] WECARE's only citation to the "gold standard" is to a reference in comments submitted to the rulemaking file by a leading opponent to ergonomics regulation. Companies' Brief at 47.

animal and/or epidemiological evidence that did not include human RCTs. *See Aviation West*, 138 Wn.2d 413, 980 P.2d 701 (1999), *Rios*, 145 Wn.2d 483, 39 P.3d 961 (2002), *Asarco, Inc. v. OSHA*, 746 F.2d 483 (9th Cir. 1984), *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986). *See generally* Occupational Safety and Health Law 446 (Randy S. Rabinowitz ed. 2d Ed.) (noting that "OSHA's reliance on a limited body of epidemiology evidence or animal studies" to demonstrate risk to workers has been "repeatedly challenged by industry with little success outside the Fifth Circuit.")

It is telling that expert bodies such as NIOSH and the NAS did not find it necessary to await the results of additional RCTs before concluding that existing research shows a strong association between workplace exposure to MSD risk factors and the development of MSDs. After a comprehensive review of the then-available evidence, NAS concluded that:

> There is a higher incidence of reported pain, injury, loss of work, and disability among individuals who are employed in occupations where there is a high level of exposure to physical loading than for those employed in occupations with lower levels of exposure.

National Academy of Sciences, Work-Related Musculoskeletal Disorders: A Review of the Evidence, AR 104093.[19]

The NAS also reviewed available research on ergonomic interventions. The NAS concluded that "[r]esearch clearly demonstrates that specific interventions can reduce the reported rate of musculoskeletal disorders for workers who perform high-risk tasks." *Id.*

Similarly, following a comprehensive review of more than 600 studies, NIOSH concluded:

> A substantial body of credible epidemiologic research provides strong evidence of an association between [musculoskeletal disorders] and certain work-related physical factors when there are high levels of exposure and especially in combination with exposure to more than one physical factor (e.g., repetitive lifting of heavy objects in extreme or awkward postures.)

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[19] The National Academy of Sciences is a private, Congressionally-chartered organization of scholars engaged in scientific and engineering research. By virtue of its Congressional charter, the NAS is required to advise the federal government on scientific and technical matters. In 1998, at the request of members of Congress, the NAS convened a workshop of experts from various disciplines to review the evidence on the relationship between the workplace and the development of MSDs. The workshop's conclusions were published, AR 104093, and subsequently presented in a comprehensive report. National Academy of Sciences, Work-Related Musculoskeletal Disorders (1999).

NIOSH, Musculoskeletal Disorders and Workplace Factors, AR 104103.[20] While acknowledging the obvious point that additional research would increase the understanding of the relationship between the workplace and MSDs, neither the NAS nor NIOSH was deterred in making its conclusions by the lack of RCT evidence sought by WECARE.

Nor are RCTs considered to be intrinsically superior to other types of epidemiological evidence. The National Academy of Sciences has explained that no one study design is inherently preferable; rather, the strength of a study depends on its adherence to various research criteria, not study design. National Academy of Sciences, Work-Related Musculoskeletal Disorders 10

[20] NIOSH, established by Congress in the Occupational Safety and Health Act, 29 U.S.C. 671, is the federal agency charged with researching safety and health hazards and making recommendations for workplace safety and health standards.

(1999).[21] And, RCTs have numerous shortcomings and severe limitations when they are used to evaluate workplace interventions, including a variety of ethical and practical problems.[22] As the NAS has explained:

> [w]hile the randomized controlled design is powerful for testing the effectiveness of interventions, it is not appropriate for all situations. For example, if the data from basic and epidemiologic studies and clinical experience suggest that the proposed intervention is highly likely to be effective, then questions can arise about how ethical it would be to withhold an

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[21] The NAS report explains that there are five criteria that are normally considered in determining whether the scientific evidence supports a cause and effect relationship: temporal ordering, cause and effect covary, absence of other plausible explanations for the observed effect, temporal contiguity, and congruity between cause and effect. NAS, Work-Related Musculoskeletal Disorders, at 9-10. These criteria, and not the type of research design, were the most important considerations for NAS in evaluating the evidence on ergonomics. *Id. See also* Vineis, Causality Assessment and Ethics in Epidemiological Research, *in* Encyclopaedia of Occupational Health and Safety 28.27 (International Labour Organization 1998) ("Although it has been claimed that inferences in observational epidemiology are weak because of the non-experimental nature of the discipline, there is no built-in superiority of randomized controlled trials or other types of experimental design over well-planned observation").

[22] The Companies' analogy to the use of randomized controlled trials by the Food and Drug Administration in approving medical treatments is misplaced. Companies' Brief at 46-47. The Federal Food, Drug and Cosmetic Act is a different statute, has an entirely different purpose, and is governed by entirely different criteria than WISHA. The fact that RCTs are used to prove the efficacy of medical *treatments* has no bearing on the type of evidence that should be required in adopting preventive rules to reduce workplace exposure to known risk factors in order to prevent injuries from occurring in the first place.

intervention from a group for the sake of a formal comparison.

National Academy of Sciences, Musculoskeletal Disorders and the Workplace: Low Back and Upper Extremities (2001), at 70. In addition, "[r]andomized trials are difficult to conduct in the workplace because work practices change frequently, workers are reassigned frequently, and it is difficult to mask participants in this setting." *Id.* at 71.[23]

For this reason, RCTs have never been required to show the effectiveness of a workplace safety or health rule. Rather, agencies are permitted to develop estimates from available sources and make reasonable predictions about the outcome of their rules. *See National Grain and Feed Ass'n v. OSHA*, 866 F.2d 717, 737 (5th Cir. 1988) (agency reasonably concluded that the presence of less grain dust would reduce the risk of grain dust explosions); *see also Asarco, Inc. v. OSHA*, 746 F.2d 483, 492 n.15 (9th Cir. 1984) ("[w]e reject the notion that the Secretary must have studies at or quite near

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[23] *See also* Zwerling et al., Design and Conduct of Occupational Injury Intervention Studies: A Review of Evaluation Strategies, American Journal of Industrial Medicine, 32:164-179 (1997) (pointing out practical and ethical difficulties in using randomized controlled trials to evaluate workplace safety interventions).

a [permissible exposure limit] that may not exist before he may set such a PEL.").

Finally, if and when other RCTs eventually become available, they are unlikely to provide all the answers about the precise relationship between MSD risk factors and the development of MSDs. But more to the point, WISHA does not require, or even contemplate, waiting for such scientific certainty. Courts have recognized that "[s]cience does not work that way." *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1495 (D.C. Cir. 1986).

In rejecting a similar argument that regulation of a workplace hazard should await further research because existing studies "do[] not answer all of the technically complex questions," the Third Circuit emphasized the agency's statutory duty to move forward with worker protection rules based upon the available evidence:

> [The] broad assertion that the [latest] study "does not answer all of the technically complex questions" . . . is obviously true, but without more it is irrelevant, for the Occupational Safety and Health Act does not require scientific certainty in the rulemaking process. Indeed, read fairly, the Act virtually forbids delay in pursuit of certainty – it requires regulation "on the basis of the best available evidence," and courts have warned that

> "OSHA cannot let workers suffer while it awaits the Godot of scientific certainty."

Public Citizen Health Research Group v. Chao, 2002 U.S. App. LEXIS 26778, *35-36 (3rd Cir. Dec. 24, 2002). *See also AFL-CIO v. Marshall*, 617 F.2d 636, 668 n. 196 (D.C. Cir. 1979), *aff'd sub nom. ATMI v. Donovan*, 452 U.S. 490, 101 S.Ct. 2478, 69 L.Ed. 2d 185 (1981) ("There seems no limit to petitioners' claim that OSHA has to wait for a pending study before promulgating the standard. After that study, there would always be another study, and then another, that could be deemed a necessary contribution to the regulation.")

The Department was right to move forward to protect workers based on the "best *available* evidence," and to not become "paralyzed by debate." *See Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1497 (D.C. Cir. 1986) (citing legislative history of the Occupational Safety and Health Act). Where, as here, the record contains "evidence from which a reasonable conclusion could be drawn that [] a regulation is necessary to protect worker health," *Aviation West*, 138 Wn.2d at 429, protection of workers

cannot wait. Under WISHA, the agency must act. *Rios v. Dept. of Labor and Industries*, 145 Wn.2d 483, 508, 39 P.3d 961 (2002).

D. The Department Correctly Determined that the Ergonomics Rule Will Be Effective in Preventing Work-Related MSDs

In making the necessary determination under the Administrative Procedure Act that the benefits of the ergonomics rule will exceed its costs, *see* RCW 34.05.328, the Department relied in part on case studies of ergonomic interventions already implemented by employers.[24] As the Department explained in the CES, ergonomics programs are already in place in many workplaces in Washington and across the United States. CES at 45-50. The rulemaking file contains many examples of employers who have voluntarily instituted ergonomics interventions to address MSDs in their workplaces, and who have experienced significant reductions in

[24] As the Department explains in its brief, *see* Department's Brief at 44-45, the case studies were only one part of the evidence relied upon by the agency in making its effectiveness estimates. The Department also relied upon scientific studies which allowed the agency to estimate the impact of reducing exposure to certain MSD risk factors. Intervenors concur with the Department's position as to why its actions met or exceeded its statutory obligations, and we will not repeat them here.

injuries and their attendant costs.[25] Some of these examples, including ergonomics programs at GTE, Seattle City Light, Xerox, and other companies, were described by the Department in the CES. CES at 49-50. Numerous other case studies appear in the record but were not utilized by the Department in estimating the effectiveness of the ergonomics rule because the Department insisted on greater detail for the case studies used in its analysis.[26] CBA at 46, AR 118073.

WECARE criticizes the Department's use of case studies as one of the bases for estimating the effectiveness of the ergonomics rule, claiming that the studies are inherently biased and unscientific. Companies' Brief at 31-32. However, case studies are an accepted

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[25] At the same time, the rulemaking record also contains overwhelming evidence demonstrating the urgent need for the ergonomics rule. The unfortunate reality is that the majority of Washington employers have not voluntarily acted to address MSD hazards in their workplaces. According to a survey conducted by the Department as part of this rulemaking, 6 out of 10 employers have taken no steps to address MSD hazards, including 4 out of 10 employers in workplaces where employers were aware that work-related MSDs have actually occurred. CES at 3, AR 117633.

[26] Some of these examples include programs at the City of Portland, AR 104284-298, Deere's Davenport Works, AR 113142-113150, the Tacoma Dome, AR 104322-324; Red Wing Shoes, AR 108973; Eastman Chemical Company, AR 108929, Georgia-Pacific, AR 104254-56, Fieldcrest-Cannon, AR 106687, and more.

base of evidence to utilize in determining whether employers will be able to comply with safety and health rules and in estimating how effective the rules will be.

When federal OSHA adopts standards, it is required to assess the costs and benefits of its rules pursuant to Presidential Executive Order, *see* Executive Order 12866, and its analyses are subject to rigorous review by the Office of Management and Budget. OSHA routinely relies on case studies in gauging the likely effectiveness of its rules, with OMB approval. A few illustrative examples follow.

OSHA's rules on "process safety management" require employers in the petrochemical industry, among others, to conduct a variety of analyses, implement control measures, and train workers to prevent explosions and other catastrophic releases of toxic materials. 29 CFR 1910.119. OSHA estimated that its rule would prevent 40 percent of the fatalities and injuries caused by such hazards in the first five years of the rule's operation, and 80 percent of fatalities and injuries thereafter. 57 Fed. Reg. 6402 (Feb. 24, 1991). These estimates were based in part on articles in trade

journals and other information submitted to the record by individual companies detailing the effectiveness of their own safety programs.[27]

When OSHA adopted a "confined spaces" rule to prevent fatalities and other injuries from asphyxiation in enclosed work areas, 29 CFR 1910.146, OSHA estimated that the rule would be 85 percent effective based in part on case studies and testimony from industry representatives regarding the effectiveness of their own programs. 58 Fed. Reg. 4543 (Jan. 14, 1993).

In adopting a "lockout" standard requiring employers to institute controls to prevent amputations, fatalities, and other trauma from the sudden activation of machinery, OSHA estimated that the rule would be 85 percent effective and would prevent 122 fatalities each year. 54 Fed. Reg. 36685 (Sept. 1, 1989). The regulatory analysis accompanying the final rule does not explain how the 85 percent effectiveness figure was derived. In reviewing the rule, the D.C. Circuit observed that the business petitioners in that case had

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[27] The Federal Register contains a summary of the agency's regulatory analysis. The full regulatory analysis, with supporting documentation, is publicly available in the OSHA Docket Office. Because this material is voluminous, intervenors have not attached it as exhibits to this brief, but we will do so if requested.

"not question[ed] OSHA's finding that the lockout regulation could prevent 122 fatalities and 28,400 lost workday injuries annually." *UAW v. OSHA*, 938 F.2d 1310, 1322 (D.C. Cir. 1991); *see also* 37 F.3d 665 (D.C. Cir. 1994) (upholding the lockout rule).

Thus, the Department reasonably relied on case studies to predict the effectiveness of the rule. Case studies show what employers are able to accomplish. If one employer has demonstrated its ability to implement control measures to effectively reduce WMSDs, there is every reason to expect that other employers can adapt those interventions to their workplaces and achieve similar results. Case studies are an effective and appropriate means of gauging the likely effect of a rule, and the Department reasonably relied on them here in estimating the effectiveness of the ergonomics rule.

The record provides ample evidence to conclude that the rule will be effective in preventing WMSDs. The Companies' suggestion to the contrary should be rejected.

E. The Trial Court Properly Rejected WECARE's Request to Admit Evidence Pertaining to the Federal OSHA Ergonomics Rulemaking

WECARE complains that the trial court refused to admit testimony from the federal OSHA hearings on federal OSHA's proposed ergonomics rule. Companies' Brief at 58-59. The Companies asked the trial court to admit eight pages out of hundreds of pages of testimony given by various witnesses concerning federal OSHA's Preliminary Economic Analysis (PEA).[28] The trial court wisely resisted being drawn into a sideshow over the federal OSHA rulemaking, which would have required the court to familiarize itself with not only a federal OSHA PEA of more than 1,000 pages in length, but also significant portions of transcript testimony and additional documentary evidence submitted to the federal OSHA record.

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[28] The federal OSHA rulemaking involved 44 days of public hearings, which included testimony from 714 witnesses and generated more than 18,000 pages of transcripts. 65 Fed. Reg. 68266 (Nov. 14, 2000). At least six days of hearings contained significant testimony and comments pertaining to the PEA.

V. CONCLUSION

Each year, tens of thousands of working men and women in this state are injured because their jobs involve heavy lifting, highly repetitive motion, and other hazardous tasks. Based on overwhelming evidence that these dangers are pervasive and their harms can be prevented, the Department reasonably, and correctly, concluded that an ergonomics rule was "reasonably necessary or appropriate" to protect workers. WECARE has not met its burden of showing otherwise, and its challenge to the ergonomics rule should be rejected.

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CERTIFICATE OF SERVICE

Pursuant to RCW 9A.72.085, I certify that on this 27th day of January, 2003, I caused a true and correct copy of the Brief of Intervenors American Federation of Labor and Congress of Industrial Organizations and Washington State Labor Council, AFL-CIO and this Certificate of Service to be filed via hand delivery to:

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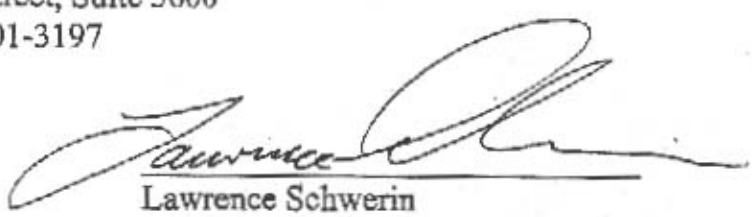

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